IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., Plaintiff, v. BAXTER HEALTHCARE CORPORATION, Defendant.	C. A. No. 06-636-GMS **JURY TRIAL DEMANDED**
BAXTER HEALTHCARE CORPORATION, Counterclaimant, v. AVENTIS PHARMA S.A., Counterdefendant.	

ANSWER TO AMENDED COMPLAINT AND COUNTERCLAIM FOR DECLARATORY JUDGMENT

Baxter Healthcare Corporation ("Baxter") hereby answers the Complaint filed by Aventis Pharma S.A. ("Aventis Pharma") as follows:

NATURE OF THE ACTION

1. Baxter admits Aventis Pharma filed an action for patent infringement of United States Patent No. 5,565,427 ("the '427 patent") and Aventis Pharma's action purports to arise under the patent laws of the United States. Except as specifically admitted, Baxter denies the allegations of paragraph 1.

2. Baxter admits: A. Nattermann & Cie GmbH ("Nattermann") and Aventis Behring L.L.C. filed suit against Baxter on April 11, 2003; Nattermann requested reexamination of the '427 patent; the parties stipulated to a dismissal of the litigation

without prejudice; the parties agreed that if either party filed a court action after a reexamination certificate issued, such court action shall be filed in the United States District Court for District of Delaware; the Court entered the dismissal on November 4, 2003; and the United States Patent and Trademark Office ("U.S. Patent Office") conducted a reexamination of the '427 patent, which is now complete. Except as specifically admitted, Baxter denies the allegations of paragraph 2.

PARTIES

3. Baxter is without sufficient information and belief to admit or deny the allegations in this paragraph and, on that basis, denies the allegations of paragraph 3.

4. Baxter admits the allegations of paragraph 4.

JURISDICTION AND VENUE

5. Baxter admits the allegations of paragraph 5.

6. Baxter admits that Baxter is a Delaware corporation and that Baxter stipulated in the prior related action to the Court's jurisdiction over any refiled action. Except as specifically admitted, Baxter denies the allegations of paragraph 6.

7. Baxter admits the allegations of paragraph 7.

8. Baxter admits venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b) and that Baxter stipulated to venue in this Court for any refiled action.

CLAIM FOR PATENT INFRINGEMENT OF THE '427 PATENT

9. Baxter admits that, on its face, the '427 patent is entitled "Stabilized Factor VIII Preparations" and appears to have issued on October 15, 1996. Except as specifically admitted, Baxter denies the allegations of paragraph 9.

10. Baxter is without sufficient information and belief to admit or deny the allegations in this paragraph and, on that basis, denies the allegations of paragraph 10.

11. Baxter is without sufficient information and belief to admit or deny the allegations in this paragraph and, on that basis, denies the allegations of paragraph 11.

12. Baxter admits that, on the face of the Reexamination Certificate, it appears the U.S. Patent Office issued a Reexamination Certificate to Aventis Behring GmbH on July 23, 2002. Except as specifically admitted, Baxter denies the allegations of paragraph 12.

13. Baxter admits that, on the face of the Reexamination Certificate, it appears the U.S. Patent Office issued a Reexamination Certificate to Nattermann on October 10, 2006. Except as specifically admitted, Baxter denies the allegations of paragraph 13.

14. Baxter denies the allegations of paragraph 14.

15. Baxter admits that the Complaint previously filed by Nattermann and Aventis Behring L.L.C. against Baxter on April 11, 2003 included allegations of infringement of the '427 patent. Except as specifically admitted, Baxter denies the allegations of paragraph 15.

16. Baxter admits that the United States Food and Drug Administration ("U.S. FDA") granted it approval on July 25, 2003 to market ADVATE® in the United States. Except as specifically admitted, Baxter denies the allegations of paragraph 16.

17. Baxter admits that ADVATE® became commercially available in the United States in August 2003. Except as specifically admitted, Baxter denies the allegations of paragraph 17.

18. Baxter denies the allegations of paragraph 18.

19. Baxter admits the allegations of paragraph 19.

20. Baxter admits that its 2000 IU dosage strength ADVATE® became commercially available in the United States in May 2006. Except as specifically admitted, Baxter denies the allegations of paragraph 20.

21. Baxter denies the allegations of paragraph 21.

22. Baxter admits the allegations of paragraph 22.

23. Baxter admits that its 3000 IU dosage strength ADVATE® became commercially available in the United States in July 2007. Except as specifically admitted, Baxter denies the allegations of paragraph 23.

24. Baxter denies the allegations of paragraph 24.

25. Baxter denies the allegations of paragraph 25.

26. Baxter denies the allegations of paragraph 26.

AFFIRMATIVE DEFENSES

Answering further, Baxter raises the following affirmative defenses to the causes of action set forth in the Complaint.

FIRST AFFIRMATIVE DEFENSE

27. Aventis Pharma is barred from obtaining any relief sought in the Complaint because Baxter has not infringed and is not infringing, literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '427 patent.

SECOND AFFIRMATIVE DEFENSE

28. Aventis Pharma is barred from obtaining any relief sought in the Complaint because the '427 patent, and each claim thereof, is invalid for failing to meet

one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103 and/or 112, as discussed more fully in the Counterclaim below.

THIRD AFFIRMATIVE DEFENSE

29. Aventis Pharma is barred from obtaining any relief sought in the Complaint by the doctrine of prosecution history estoppel.

FOURTH AFFIRMATIVE DEFENSE

30. Aventis Pharma is barred from obtaining any relief sought in the Complaint by the doctrine of unclean hands, as discussed more fully in the Counterclaim below.

FIFTH AFFIRMATIVE DEFENSE

31. Aventis Pharma is barred from obtaining any relief sought in the Complaint because the '427 patent is unenforceable due to inequitable conduct and/or fraud on the U.S. Patent Office during the initial prosecution and both reexaminations of the '427 patent, including failing to disclose, and untimely disclosure of, prior art and other information material to the patentability of the claims and making false and misleading statements in an attempt to deceive the U.S. examiner concerning the state of the art and the patentability of its claims, as discussed more fully in the Counterclaim below.

SIXTH AFFIRMATIVE DEFENSE

32. Aventis Pharma is barred from obtaining full relief sought in the Complaint by the doctrine of absolute intervening rights specified in 35 U.S.C. § 252.

SEVENTH AFFIRMATIVE DEFENSE

33. Aventis Pharma is barred from obtaining full relief sought in the Complaint by the doctrine of equitable intervening rights specified in 35 U.S.C. § 252.

COUNTERCLAIM

Baxter counterclaims against Aventis Pharma as follows:

THE PARTIES

34. Baxter is and at all relevant times has been a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

35. Upon information and belief, Aventis Pharma S.A. is a corporation with its principal place of business at 20, avenue Raymond Aron, Antony, France.

JURISDICTION AND VENUE

36. This is a counterclaim for declaratory relief under the patent laws of the United States. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

37. This Court has jurisdiction over Aventis Pharma because it has availed itself of the jurisdiction of this Court by filing the above-entitled action against Baxter and, therefore, is subject to jurisdiction herein.

38. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE CONTROVERSY

39. Baxter is a United States subsidiary of Baxter International Inc., a global healthcare company that provides critical therapies for people with life-threatening conditions primarily through three key businesses (BioScience, Medication Delivery and Renal Therapies). Baxter products and services are used to treat patients with many conditions including cancer, trauma, hemophilia, immune deficiencies, kidney disease, and other disorders. Baxter's BioScience business provides therapies using proteins derived from human blood plasma or recombinant technology to treat hemophilia, immune deficiencies, and other conditions. The protein relevant to this action is Baxter's advanced recombinant Factor VIII product, called ADVATE®.

40. Upon information and belief, Aventis Pharma is the assignee of the '427 patent. The '427 patent lists Wilfried Freudenberg ("Freudenberg") as the inventor and the assignee as Behringwerke Aktiengesellschaft. Upon information and belief, the '427 patent was assigned to Hoechst Aktiengesellschaft, who assigned the '427 patent to Centeon Pharma GmbH on or about November 7, 1997. Upon information and belief, Centeon Pharma GmbH assigned the '427 patent to Aventis Behring GmbH on or about January 26, 2000. Upon further information and belief, Aventis Behring GmbH assigned the '427 patent to Nattermann on or about March 19, 2003. Upon further information and belief, Nattermann assigned the '427 patent to Aventis Pharma on March 26, 2004. A true and correct copy of the '427 patent is attached hereto as Exhibit 1.

A. Baxter's Recombinant Factor VIII Product, ADVATE®

41. In persons (usually men and boys) suffering from hemophilia A (classic hemophilia), a clotting factor naturally found in blood, Factor VIII ("FVIII"), is either

inactive or not present in sufficient amounts to allow blood to clot normally. As a result, persons with hemophilia A can suffer uncontrolled bleeding, in particular, internal bleeding into muscles, limb joints, or organs. Such bleeding can be painful, debilitating, and ultimately life threatening.

42. Baxter introduced the first commercially-produced FVIII concentrate to treat hemophilia A in 1966. This and subsequent FVIII products were made from human blood plasma. Baxter has continuously worked to advance its FVIII products. Baxter developed the first commercially successful immunoaffinity purification method to selectively purify FVIII from plasma and cell culture media. This process, known as Method M, has been licensed to multiple third parties and has improved the quality of FVIII products.

43. Recombinant Factor VIII ("rFVIII") is produced using mammalian cells grown in culture, into which the human FVIII gene has been inserted. The cells secrete rFVIII, which is harvested and purified at a biologics manufacturing facility. In 1992, Baxter introduced its RECOMBINATE™ rFVIII product, the first genetically engineered FVIII product made using recombinant DNA technology.

44. Baxter continued to develop advances in its rFVIII therapeutics. Baxter has developed an improved rFVIII product that is manufactured using a plasma/albumin-free and serum-free method, called ADVATE®. No human or animal-derived raw materials are added to Baxter's ADVATE® product during the cell culture, purification, or formulation processes, so the margin of safety is higher than with any other FVIII product on the market.

45. Baxter received approval from the U.S. FDA for ADVATE® on or about July 25, 2003.

46. The controversy between Baxter, on the one hand, and Aventis Pharma, on the other, arises in relation to Baxter's ADVATE® product, in particular, to the specific formulation of ADVATE®.

B. The '427 Patent and Inequitable Conduct

47. The first United States application that ultimately led to issuance of the '427 patent was filed by Aventis Pharma's predecessor-in-interest (Behringwerke) with the U.S. Patent Office on or about April 7, 1992. Carol Einaudi, an attorney at the Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P law firm ("Finnegan"), represented Aventis Pharma's predecessor-in-interest during the original prosecution of the '427 patent. This application claimed priority to a foreign application filed in Germany ("German application") on or about April 9, 1991 (discussed below). The claims in the applications leading up to the '427 patent were pending before the U.S. Patent Office for over four years. The U.S. Patent Office notified Aventis Pharma's predecessor-in-interest that the then-pending claims were allowable on or about April 30, 1996. The '427 patent issued on or about October 15, 1996.

Inequitable Conduct

48. The patent statute requires those associated with a pending application to meet a duty of candor, good faith, and disclosure. In particular, "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [U.S. Patent] Office, which includes a duty to disclose to

the [U.S. Patent] Office all information known to that individual to be material to patentability … ." 37 C.F.R. § 1.56. A parallel duty requires similar candor, good faith, and disclosure during reexamination. 37 C.F.R. § 1.555. This duty of candor and disclosure has been recognized and affirmed by the federal courts. Inequitable conduct arising from the violation of this duty has resulted in courts holding issued patents unenforceable. Upon information and belief, the named inventor and all of Aventis Pharma's predecessors-in-interest's representatives associated with the prosecution of the U.S. application knew and understood their duties under 37 C.F.R. §§ 1.56 and 1.555 to disclose to the U.S. Patent Office all information known to be material to the patentability of the pending claims.

Failure to Disclose the Foreign Search Report and Narrowing Prior Art Was Inequitable Conduct

49. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest (Behringwerke) withheld material and non-cumulative prior art with the intent to deceive and/or mislead the U.S. Patent Office during the original prosecution of the '427 patent.

50. Evidence of the materiality of the prior art references cited as well as evidence of the intent to deceive and/or mislead the U.S. Patent Office appears in the European Prosecution, the Original U.S. prosecution, and the First Reexamination of the '427 patent.

European Prosecution

51. Aventis Pharma's predecessor-in-interest (Behringwerke) simultaneously prosecuted the U.S. application and a corresponding European patent application ("EP application") that was filed on or about March 21, 1992 in the European Patent Office.

The EP application also claimed priority to the German application. The claims initially filed in the applications submitted to both the U.S. Patent Office and the European Patent Office were the same.[1]

52. During examination of the EP application, in accordance with normal European Patent Office practice, a search of technical literature was conducted to determine the state of the art for the purpose of assessing the patentability of the pending claims. References identified during the search were cited in a Search Report ("1992 Search Report").

53. On or about May 20, 1992, the European Patent Office sent Aventis Pharma's predecessor-in-interest the 1992 Search Report, which identified the following references as relevant to the patentability of the EP claims: European Patent Application No. 0315 968 ("EP 968"), European Patent Application No. 0412 466 ("EP 466"), International Publication No. WO 91 10439 ("WO 439"), and Great Britain Patent No. 941 019 ("GB 019"). One of the references disclosed, EP 466, was also owned by Aventis Pharma's predecessor-in-interest (Behringwerke). EP 466 was published on or about February 13, 1991, with a priority date of August 7, 1989.

54. On or about June 26, 1995, while the U.S. application was pending and in active prosecution, the European Patent Office rejected all of the claims pending in the EP application in view of three of the references cited by the European Patent Office in

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[1] Two sets of claims were prosecuted in the EP application: (1) a set for Greece and Spain (method claims); and (2) a set for all designated states except Greece and Spain (product and method claims). The original claims filed and prosecuted in the U.S. were identical to those originally filed and prosecuted in the EP application for all designated states except Greece and Spain. The EP claims for all designated states except Greece and Spain are referred to herein as the "EP claims."

its 1992 Search Report (EP 968, EP 466, and WO 439) as well as a fourth reference, European Patent Application No. 468 181 ("EP 181"). At that time, the broadest claim, EP claim 1, recited in part, "an amino acid or one of its salts or derivatives and, where appropriate, a detergent or an organic polymer." The European Patent Office required the Applicant to limit all claims to very high purity ("VHP") FVIII, which had a specific activity greater than 1000 U/mg. The European Patent Office also rejected EP claim 8, which was already limited to VHP FVIII but not limited to a particular amino acid, as not patentable because the Applicants had only shown that VHP FVIII could be stabilized by a particular amino acid, arginine. The European Patent Office noted, "In view of [EP 968] … as well as Example 2 of the present application … it is evident that a VHP-FVIII:C preparation cannot be stabilized with any arbitrary agent containing amino acid."[2] Further, the European Patent Office also rejected EP claims 1-3 and 5-12, which recited amino acids other than either arginine or arginine in combination with glycine, as lacking novelty in view of EP 968, EP 466, WO 439, and EP 181 (each of which disclosed the use of one or more of the amino acids lysine, histidine, and glycine).

55. In addition, on or about June 26, 1995, the European Patent Office ordered that three references (EP 968, EP 466, and WO 439) be identified in the specification of the EP application and their relevance as prior art briefly described therein.

56. On or about January 2, 1996, Aventis Pharma's predecessor-in-interest responded to the rejections in the June 26, 1995 communication, amending the EP claims

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[2] Prosecution of the EP application was conducted in the German language. The excerpts quoted herein are English translations from the German-language prosecution history.

to narrow their scope and including the description of the references as required by the European Patent Office. Specifically, the claims were limited to recite only the specific amino acid "arginine, or its salts," in the recited solution, rather than any "amino acid or one of its salts or derivatives," as originally submitted. Aventis Pharma's predecessor-in-interest also amended the claims to include a limitation that the "F VIII activity [was] greater than 1000 IU/mg." Aventis Pharma's predecessor-in-interest noted, "[t]his new main claim is also demarcated from the references cited under Point 5. In [EP 968], lysine and histidine are used for the stabilization."

57. On or about January 2, 1996, Aventis Pharma's predecessor-in-interest also altered the specification of the EP application according to the European Patent Office's instructions. The added paragraph reads, "[EP 968] describes FVIII-C solutions with a specific activity of more than 1000 IU/mg with stabilizing additions of a carbohydrate, lysine, and histidine in concentrations of 0.0001 to 10 mol/l. Stabilization of FVIII:C solutions with a specific activity of 56 to 215 IU/mg by carbohydrate and glycine in a concentration of 3% (i.e. 0.4 mol/l) can be inferred from [EP 466]. Finally, [WO 439] describes an injectable FVIII:C solution which contains one or more amino acids in a concentration of 0.1 to 1.0 mol/l, and a carbohydrate."

58. The European Patent Office published the patent grant with the amended (limited) claims on or about December 10, 1997.

Original Prosecution

59. Although the claims prosecuted in the U.S. application were originally identical to those prosecuted in the EP application, and Aventis Pharma's predecessor-in-interest clearly had knowledge of the prior art references cited by the European Patent

Office during its prosecution of the U.S. application, Aventis Pharma's predecessor-in-interest did not disclose the references in the 1992 Search Report to the U.S. Patent Office and did not disclose the modification to the specification to identify these references, as required by the European Patent Office. Aventis Pharma's predecessor-in-interest similarly failed to disclose that the same claims in the EP application had to be significantly narrowed to include the specific amino acid, arginine, to gain allowance.

60. Aventis Pharma's predecessor-in-interest had at least four opportunities to disclose to the U.S. Patent Office the prior art references identified by the European Patent Office in the 1992 Search Report, as it subsequently submitted four substantive amendments to the U.S. Patent Office (on or about September 9, 1993; December 13, 1994; August 24, 1995; and February 29, 1996). All of the amendments were submitted after the date Aventis Pharma's predecessor-in-interest was advised by the European Patent Office of the relevant prior art the European Patent Office had found. Nevertheless, Aventis Pharma's predecessor-in-interest failed to disclose these material references (especially, EP 968, EP 466, and WO 439) to the U.S. Patent Office.

61. Aventis Pharma's predecessor-in-interest also failed to cite EP 181 even though it submitted two substantive amendments (on or about August 24, 1995 and February 29, 1996) after the European Patent Office cited this reference in the first rejection of the EP claims on or about June 26, 1995. Aventis Pharma's predecessor-in-interest knew the references cited in the 1992 Search Report and EP 181 were material to patentability of the U.S. claims because Aventis Pharma's predecessor-in-interest narrowed the EP claims and amended the specification in the EP application in response to the European Patent Office's June 26, 1995 rejection in light of these references.

First Reexamination

62. Aventis Pharma's predecessor-in-interest (Aventis Behring GmbH) filed a Reexamination Request in the U.S. Patent Office on or about May 30, 2001, requesting the U.S. Patent Office reexamine the claims of the '427 patent ("First Reexamination"). Carol Einaudi and Sanya Sukduang of Finnegan represented Aventis Pharma's predecessor-in-interest during the First Reexamination (Carol Einauidi also represented Behringwerke during the original prosecution).

63. In its Reexamination Request, Aventis Pharma's predecessor-in-interest belatedly disclosed the references cited by the European Patent Office (EP 968, EP 466, WO 439, GB 019, and EP 181) together with 11 other references. Granting Aventis Pharma's predecessor-in-interest's Reexamination Request, the U.S. Patent Office found the EP 181 reference and the GB 019 reference (in combination with U.S. Patent No. 5,605,884) raised substantial new questions of patentability as to all of the claims (claims 1-13) of the '427 patent. The U.S. Patent Office further stated the U.S. or Australian patents corresponding to the EP 968, EP 466, and WO 439 references were material to the patentability of claims 1-13 and there was a substantial likelihood a reasonable examiner would consider these references important in deciding whether or not claims 1-13 of the '427 patent were patentable.

64. In its Reexamination Request, Aventis Pharma's predecessor-in-interest again failed to expressly advise the U.S. Patent Office that the European Patent Office had rejected claims identical to those originally pending in the U.S. Patent Office and had required that the claims be limited to arginine. Moreover, Aventis Pharma's predecessor-in-interest provided no credible explanation of why the references cited in the 1992

Search Report were not disclosed to the U.S. Patent Office during the original prosecution of the application for the '427 patent.

65. Though Aventis Pharma's predecessor-in-interest disclosed in the First Reexamination the references cited by the European Patent Office (all of which the U.S. Patent Office deemed to be material to patentability of the prosecuted claims), this belated disclosure could not and did not cure the intentional failure of Aventis Pharma's predecessor-in-interest to disclose these material references during the original prosecution of the '427 patent.

66. During the First Reexamination of the '427 patent, Aventis Pharma's predecessor-in-interest also misled the U.S. Patent Office about the significance of the amendments required by the European Patent Office during the prosecution of the EP application. Aventis Pharma's predecessor-in-interest misleadingly stated that "[i]t is notable that at the end of the oral proceedings in the European Patent Office, which were concluded on or about May 16, 2001, the European Freudenberg patent was maintained unchanged from its original grant." Simply dropping a footnote, Aventis Pharma's predecessor-in-interest stated, "[t]he claims of the European Freudenberg patent differ from those of the '427 patent in that the addition of a detergent or organic polymer is optional and the amino acid is limited to only arginine." As stated above, however, the claims of the '427 patent require the addition of a detergent or organic polymer and are not limited to only arginine. The juxtaposition of these statements reveals Aventis Pharma's predecessor-in-interest minimized the significance of the amendments it was required to make to gain allowance of the European claims. At the same time it emphasized its claims survived opposition without change, it did not clearly acknowledge

the amendments to both the claims and the specification required by the European Patent Office before granting the European patent.

Nondisclosure of the 1992 Search Report and Narrowing Prior Art Was Inequitable Conduct

67. Upon information and belief, Baxter alleges that the references cited in the 1992 Search Report are material and non-cumulative prior art because they disclose elements of the '427 patent not disclosed by the references cited by the U.S. Patent Office during the original prosecution of the application that became the '427 patent. The U.S. Patent Office confirmed the materiality of these references during the First Reexamination when it explicitly stated that there was a substantial likelihood a reasonable examiner would consider these references important in deciding whether or not the claims of the '427 patent were patentable.

68. Upon information and belief, Baxter alleges that Aventis Pharma and/or its predecessors-in-interest withheld the references cited in the 1992 Search Report with the intent to deceive and/or mislead the U.S. Patent Office in an attempt to avoid limitation of the U.S. claims in light of these references as occurred with the EP claims. During the European prosecution, Aventis Pharma's predecessor-in-interest was forced to limit its claims to FVIII solutions containing arginine with a specific activity of greater than 1000 IU/mg. Aventis Pharma's predecessor-in-interest had at least four opportunities to disclose the references cited in the 1992 Search Report to the U.S. Patent Office during the original prosecution of the '427 patent, but failed to do so. Moreover, during the First Reexamination, Aventis Pharma's predecessor-in-interest failed to expressly advise the U.S. Patent Office of the limitations required of the European counterpart (FVIII solution containing arginine with a specific activity greater than 1000

IU/mg). In fact, Aventis Pharma's predecessor-in-interest attempted to direct attention away from these limitations by arguing that the European counterpart survived opposition proceedings unchanged, and merely dropped a footnote explaining that the European counterpart was limited to solutions containing arginine, without discussing the significance of such limitation.

69. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest withheld material and non-cumulative prior art with the intent to deceive and/or mislead the U.S. Patent Office during the original prosecution of the '427 patent constituting inequitable conduct.

Failure to Disclose Test Data Was Inequitable Conduct

70. Baxter is informed and believes, and based on this information and belief alleges, that:

a. Aventis Pharma's predecessor-in-interest, Aventis Behring GmbH (through its U.S. attorneys, Carol Einaudi and Sanya Sukduang, each of Finnegan), knew of, yet intentionally withheld during the First Reexamination (May 30, 2001-July 23, 2002), information material to the patentability of the '427 patent claims ("Test Data"). The Test Data was described in a submission by Baxter to the European Patent Office on April 27, 2000 during an opposition proceeding against the European equivalent of the '427 patent (attached hereto as Exhibit 2). Aventis Behring GmbH knew of the Test Data because it defended the European opposition (after a change in name from Centeon Pharma GmbH), in which the Test Data was submitted in April 2000. Aventis Behring GmbH also conducted the First Reexamination of the '427 patent

(through Carol Einaudi and Sanya Sukduang, each of Finnegan) in 2001 and 2002, after learning of the Test Data, but did not disclose the Test Data to the U.S. Patent Office.

b. Aventis Pharma's predecessor-in-interest, Nattermann (also through Carol Einaudi and Sanya Sukduang, each of Finnegan), intentionally withheld the same material Test Data during the Second Reexamination (October 21, 2003-October 10, 2006). Nattermann knew of the Test Data prior to the Second Reexamination (which lasted from October 2003 until October 2006) because the Test Data was produced to Nattermann (through its U.S. attorneys, Finnegan) by Baxter in the prior related action in September 2003. Though Nattermann (through its U.S. attorneys, Finnegan) provided selected materials from the prior related action to the U.S. Patent Office in the Second Reexamination, it did not disclose the Test Data to the U.S. Patent Office.

c. Aventis Pharma (again through Carol Einaudi and Sanya Sukduang, each of Finnegan), intentionally withheld the same material Test Data during the Second Reexamination. Though Aventis Pharma (through its U.S. attorneys, Finnegan) provided selected materials from the prior related action to the U.S. Patent Office in the Second Reexamination, it did not disclose the Test Data to the U.S. Patent Office.

71. The Test Data replicated the formulations in example 2 in the EP and '427 patents with rFVIII. Retained specific activities were evaluated in two tests: (1) under the identical conditions of example 2 in the EP and '427 patents (see Table 3, below); and (2) under the conditions of example 2 in the EP and '427 patents, but with 4mM of $CaCl_2$

added to each solution (see Table 4, below).

Table 3 (Excerpted): Actual and expected activity achieved with the stabilization solutions of Example 2

Mixture	$CaCl_2$ (mM)	Actual retained activity (%)	Expected Retained Activity, according to Example 2 of the patent (%)
I		66.33	39.3
II	2.5	92.40	35.1
III		36.01	82.4
IV		46.20	96.2

Table 4 (Excerpted): Actual retained activities achieved with the addition of 4 mM $CaCl_2$

Mixture	$CaCl_2$ (mM)	Actual retained activity (%)	Expected Retained Activity, according to Example 2 of the patent (%)
I	4	95.48	39.3
II	6.5	93.78	35.1
III	4	97.15	82.4
IV	4	100.55	96.2

72. The Test Data from the first test (reported in Table 3) reported results using the identical four formulations as those disclosed in example 2 in the '427 patent. As the results show, the levels of retained specific activity for rFVIII formulations differed greatly from the levels of retained specific activity disclosed in Table 2 of the '427 patent. The only formulation from the first test with retained specific activity greater than 90% was the one with $CaCl_2$ (Mixture II in Table 3). In Table 2 of the '427 patent, the opposite result is reported: the same formulation had the lowest level of retained specific activity (35.1%).

73. In the second test (Test Data reported in Table 4) 4 mM of $CaCl_2$ was added to all four formulations disclosed in example 2 of the '427 patent. The Test Data

from the second test shows that all four formulations had retained specific activities greater than 90% in contrast to the data reported in Table 2 of the '427 patent. Thus, the Test Data demonstrated that $CaCl_2$ must be included in rFVIII formulations to obtain retained levels of specific activity greater than 90%.

74. Upon information and belief, Baxter alleges that the Test Data is material because it shows the '427 patent would not enable one of ordinary skill in the art to practice the claimed invention. First, the '427 patent does not teach that the inclusion of calcium chloride ($CaCl_2$) is necessary to stabilize a rFVIII formulation. And, a skilled artisan would not have appreciated this requirement at the time the application leading to the '427 patent was filed. Moreover, the sole formulation disclosed in example 2 in the EP and '427 patents that contains $CaCl_2$ was reported to have very low retained specific activity. Such a result would direct a skilled artisan away from the inclusion of $CaCl_2$, not towards it. (*See* Exhibit 2, p. 10.) Second, as the Test Data show, the results in Table 2 in the EP and '427 patents were not reproducible, calling into question the validity of the experimental results reported in the '427 patent.

75. Although the Test Data was before the European Patent Office, the European Patent Office did not consider the relevance of the Test Data to patentability as it held that the Test Data was submitted too late in the opposition process. Even though the European Patent Office did not consider the impact of the Test Data on patentability when it rendered its decision, the European Patent Office did acknowledge that the Test Data showed different results than those disclosed in Table 2 in the EP patent (which is the same as Table 2 in the '427 patent). This fact confirms the materiality of the Test Data.

76. In the First and Second Reexaminations, Aventis Pharma or its predecessors-in-interest continued to prosecute the '427 patent claims, yet did not submit the critical Test Data from the first and second tests that demonstrated the prosecuted claims were not patentable. Due to Aventis Pharma's and/or its predecessors-in-interest's failure to disclose the Test Data, the examiner who determined the patentability of the '427 patent was not made aware of the significance of $CaCl_2$ to the claimed formulations or that the data disclosed in the '427 patent was not reproducible.

77. Upon information and belief, Baxter alleges that Aventis Pharma and/or its predecessors-in-interest (through at least their U.S. and European patent attorneys/agents, including Finnegan) knew of the materiality of the Test Data before the First and Second Reexaminations. There is a substantial likelihood a reasonable examiner would have considered the Test Data to be material and that such a reasonable examiner would have used the Test Data to determine whether or not the claims of the '427 patent were patentable.

78. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma and/or its predecessors-in-interest (Aventis Behring GmbH and Nattermann) (through Carol Einaudi and Sanya Sukduang, each of Finnegan) intentionally withheld material Test Data with the intent to deceive and/or mislead the U.S. Patent Office during the First Reexamination and the Second Reexamination of the '427 patent. The actions of Aventis Pharma and/or its predecessors-in-interest (Aventis Behring GmbH and Nattermann) (through Carol Einaudi and Sanya Sukduang, each of Finnegan) constitute inequitable conduct.

Submission of a False Declaration Was Inequitable Conduct

79. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest (Aventis Behring GmbH) submitted a false affidavit during the First Reexamination.

80. The U.S. examiner initially rejected the claims in the First Reexamination, stating it would have been obvious to combine the purified FVIII described in U.S. Patent No. 4,495,175 ("Chavin") with the viral inactivation method described in U.S. Patent No. 4,446,134 ("Naito"). Chavin discloses highly purified human FVIII (4,000 to 8,000 IU/mg) that is sterile filtered to sterilize purified FVIII preparations derived from blood; Naito discloses the use of an amino acid and carboxylic acid salt (a detergent) for heat treatment to inactivate hepatitis virus in FVIII preparations derived from blood. The U.S. examiner, therefore, rejected claims 1, 2, 4, and 7-11 of the '427 patent because the combination of Naito and Chavin would render these claims obvious.

81. To overcome this rejection, Aventis Pharma's predecessor-in-interest submitted a conclusory declaration of Dr. Albrecht Gröner, which asserted that a person of ordinary skill in the art would not be motivated to combine the Naito and Chavin references because the purified FVIII preparation of Chavin "does not need to be sterilized, and cannot and does not contain an infective dose of hepatitis virus." Neither Aventis Pharma's predecessor-in-interest nor Dr. Gröner submitted any experimental data or references to allow the U.S. examiner to consider the probative value of Dr. Gröner's bare opinion. Upon information and belief, and based on pertinent references in the field, the ability of a particular purification method (such as that disclosed in Chavin) to remove hepatitis virus from a blood-derived product cannot be predicted and must be

determined empirically through experimentation. Thus, the opinion in Dr. Gröner's declaration, upon which the U.S. Patent Office relied in confirming the claims of the '427 patent, could not be made without experimental data to support it. Upon information and belief, Aventis Pharma's predecessor-in-interest's submission of Dr. Gröner's declaration (without any supporting experimental data) was an intentional attempt to deceive the U.S. Patent Office.

82. Aventis Pharma's predecessor-in-interest (Nattermann) filed a Second Reexamination Request on or about October 21, 2003, requesting another reexamination of the claims of the '427 patent ("Second Reexamination"). The U.S. Patent Office granted this request on or about December 22, 2003. During the Second Reexamination, Carol Einaudi and Sanya Sukduang of Finnegan represented Aventis Pharma's predecessor-in-interest as they had during the First Reexamination.

83. During the Second Reexamination, Aventis Pharma's predecessor-in-interest also inaccurately asserted the conclusory opinions provided in Dr. Gröner's First Reexamination declaration were accurate and credible. Aventis Pharma's predecessor-in-interest again failed to offer supporting experimental data for Dr. Gröner's opinions.

84. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest submitted a false declaration with the intent to deceive and/or mislead the U.S. Patent Office during the First and Second Reexaminations of the '427 patent constituting inequitable conduct.

Failure to Disclose Prior Art Owned by Patentee Was Inequitable Conduct

85. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest (Aventis Behring) withheld material and non-cumulative prior art with the intent to deceive and/or mislead the U.S. Patent Office during the First Reexamination.

86. Upon information and belief, U.S. Patent No. 4,758,657 ("Farb") was assigned to Armour Pharmaceutical Company ("Armour") prior to grant of the patent (on or about July 19, 1988). Upon information and belief, on or about February 22, 1995, Armour and Behringwerke combined their respective blood plasma derivative businesses into a worldwide joint venture called Centeon Pharma GmbH ("Centeon"). Upon further information and belief, Centeon subsequently became Aventis Behring when Armour's parent company (Rhone-Poulenc Rhorer) and Behringwerke's parent company (Hoechst Aktiengesellschaft) merged to form Aventis Pharmaceuticals on or about December 15, 1999. Therefore, upon information and belief, Aventis Behring was the sole owner of both the '427 patent and Farb on or about December 15, 1999.

87. Despite being the sole owner of Farb, Aventis Pharma's predecessor-in-interest (Aventis Behring) failed to disclose Farb to the U.S. Patent Office when it filed its First Reexamination Request on or about May 30, 2001. In fact, Aventis Pharma's predecessor-in-interest only disclosed Farb to the U.S. Patent Office after Baxter stated its intention to use Farb to invalidate the '427 patent during the previous related action filed against Baxter on April 11, 2003. Instead of proceeding with the litigation it filed, Aventis Pharma's predecessor-in-interest dismissed the previous action against Baxter and filed a request for an *ex parte* Second Reexamination on or about October 21, 2003.

Along with the Second Reexamination Request, Aventis Pharma's predecessor-in-interest filed a request to add claims 14-22.

88. Although Aventis Pharma's predecessor-in-interest disclosed Farb in the Second Reexamination, this belated disclosure could not and did not cure the intentional failure of Aventis Pharma's predecessor-in-interest to disclose this material reference during the First Reexamination of the '427 patent.

89. Granting Aventis Pharma's predecessor-in-interest's Second Reexamination Request, the U.S. Patent Office found Farb raised "a substantial new question of patentability as to claims 1-3, 5-7, and 11." Three of the remaining claims – claims 4, 12, and 13 – were already limited to solutions containing arginine. Since the final remaining claims 8 and 9 were dependent upon claim 1, the only claims unaffected by Farb were claims that already included the arginine limitation.

90. On or about June 1, 2004, the U.S. Patent Office rejected claims 1-3, 5-9, 11, 13, and 20 as being anticipated by Farb. The U.S. Patent Office stated that Farb "discloses a factor VIII:C solution having identical components as the presently claimed solution." Moreover, the "specific activit[ies] of the factor VIII:C in the factor VIII:C solutions disclosed in Farb are 140 U/mg, 1200 U/mg, and 1800 U/mg."

91. On or about December 21, 2004, the U.S. Patent Office upheld its previous rejections and rejected Aventis Pharma's predecessor-in-interest's argument that Farb does not anticipate the '427 patent. The U.S. Patent Office ultimately issued a Reexamination Certificate on or about October 10, 2006, but only after the claims, except claim 11 and those claims limited to arginine, had been substantively amended to avoid anticipation by Farb.

92. Upon information and belief, Baxter alleges that Farb is material and non-cumulative prior art because most of the claims of the '427 patent were limited to avoid anticipation by Farb.

93. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest withheld material and non-cumulative prior art with the intent to deceive and/or mislead the U.S. Patent Office during the First Reexamination of the '427 patent constituting inequitable conduct.

Submission of Misleading Statements About The Prior Art Was Inequitable Conduct

94. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest (Nattermann) submitted misleading statements during the Second Reexamination.

95. Aventis Pharma's predecessor-in-interest also misleadingly characterized statements in the Roser patent and prosecution history regarding the alleged instability of "high-salt" FVIII solutions. In an attempt to distinguish the claims from Farb, Aventis Pharma's predecessor-in-interest asserted that the examples in U.S. Patent No. 6,649,386 ("Roser patent") show that Farb's solutions (FVIII in liquid form) are "unstable" because of their allegedly high salt content. However, the Roser patent shows only that, *when dried*, certain "high salt" formulations of FVIII lose modest amounts of activity after six weeks of storage at high temperatures. The Roser patent does not describe any measurements of FVIII solutions, as described in Farb, over any time period under any conditions. Aventis Pharma's predecessor-in-interest also focused on a self-serving statement made during prosecution of the Roser patent that Farb allegedly did not teach inclusion of "stabilizers capable of imparting ambient storage stability." The quoted

statement is false because Farb teaches the inclusion of a basic amino acid and a detergent to retard losses of FVIII activity, and both of these stabilizers are present in each of the Roser patent's FVIII formulations. Moreover, the quoted statement from the Roser patent flatly contradicts Aventis Pharma's predecessor-in-interest's position during prosecution of the '427 patent and in the prior action because each of the claims of the '427 patent recites an amino acid and a detergent (or organic polymer). Indeed, an amino acid and a detergent (or organic polymer) are the *only* necessary stabilizers in several of Aventis Pharma's asserted claims (*e.g.*, claims 8, 11, 14, 21, and 23). Aventis Pharma's predecessor-in-interest's misleading and incorrect use of the Roser patent was a transparent attempt to avoid anticipation by Farb.

96. Baxter is informed and believes, and based on this information and belief alleges, that Aventis Pharma's predecessor-in-interest submitted misleading statements with the intent to deceive and/or mislead the U.S. Patent Office during the Second Reexamination of the '427 patent constituting inequitable conduct.

97. An actual and justiciable controversy exists between the parties regarding the noninfringement, invalidity, and unenforceability of the '427 patent. Baxter therefore seeks a judicial determination that it does not infringe any valid and enforceable claim of the '427 patent and that the '427 patent is invalid and unenforceable.

FIRST CLAIM FOR RELIEF

(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '427 PATENT)

98. Baxter incorporates herein by reference Paragraphs 1 through 82 above.

99. An actual controversy has arisen and now exists between the parties with respect to Baxter's noninfringement of the claims of the '427 patent. As shown by oral

and written communications with Baxter, the first Complaint filed April 11, 2003, and the present Complaint filed October 16, 2006, Aventis Pharma or its predecessor-in-interest contends Baxter infringes the '427 patent. Baxter contends that it does not infringe any valid and enforceable claim of the '427 patent.

100. Pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to the noninfringement of the '427 patent is necessary and appropriate under the circumstances.

SECOND CLAIM FOR RELIEF

(DECLARATORY JUDGMENT OF INVALIDITY OF THE '427 PATENT)

101. Baxter incorporates herein by reference Paragraphs 1 through 82 above.

102. An actual controversy has arisen and now exists between the parties with respect to the invalidity of the '427 patent. As shown by oral and written communications with Baxter, the first Complaint filed April 11, 2003, and the present Complaint filed October 16, 2006, Aventis Pharma or its predecessors-in-interest contends that the '427 patent is valid. Baxter contends that the '427 patent is invalid for failure to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, and/or 112.

103. Pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to the invalidity of the '427 patent is necessary and appropriate under the circumstances.

THIRD CLAIM FOR RELIEF

(DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '427 PATENT)

104. Baxter incorporates herein by reference Paragraphs 1 through 82 above.

105. An actual controversy has arisen and now exists between the parties with respect to the unenforceability of the '427 patent. As shown by oral and written communications with Baxter, the first Complaint filed April 11, 2003, and the present Complaint filed October 16, 2006, Aventis Pharma or its predecessors-in-interest contends that the '427 patent is enforceable. Baxter contends that the '427 patent is unenforceable based on Aventis Pharma's inequitable conduct arising from its failure to comply with 37 C.F.R. § 1.56 and 37 C.F.R. § 1.555 as described more fully in paragraphs 42 to 82, *supra*.

106. Pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to the unenforceability of the '427 patent is necessary and appropriate under the circumstances.

PRAYER

WHEREFORE, Baxter Healthcare Corporation requests entry of judgment in its favor and against Aventis Pharma S.A. as follows:

1. Holding that Aventis Pharma S.A. take nothing by way of its Complaint;

2. Holding that Baxter Healthcare Corporation's 250, 500, 1000, 1500, 2000 and 3000 dosage strength ADVATE® products do not infringe, literally or under the doctrine of equivalents, either directly or indirectly, any valid claim of U.S. Patent No. 5,565,427;

3. Declaring Baxter Healthcare Corporation's 250, 500, 1000, 1500, 2000 and 3000 dosage strength ADVATE® products do not infringe, literally or under the doctrine of equivalents, either directly or indirectly, any valid claim of U.S. Patent No. 5,565,427;

4. Holding that Baxter Healthcare Corporation did not willfully infringe the claims of United States Patent No. 5,565,427;

5. Declaring Baxter Healthcare Corporation did not willfully infringe the claims of United States Patent No. 5,565,427;

6. Holding that the claims of United States Patent No. 5,565,427 are invalid;

7. Declaring the claims of United States Patent No. 5,565,427 invalid;

8. Holding that the claims of United States Patent No. 5,565,427 are unenforceable;

9. Declaring United States Patent No. 5,565,427 and the claims therein unenforceable;

10. Decreeing that Baxter Healthcare Corporation is permitted to continue the manufacture, use, offer for sale, or sale of 250, 500, 1000, 1500, 2000 and 3000 dosage strength ADVATE® products in the United States and to import 250, 500, 1000, 1500, 2000 and 3000 dosage strength ADVATE® products into the United States;

11. Decreeing this case an "exceptional case" within the meaning of 35 U.S.C. § 285 and awarding reasonable attorney fees to Baxter Healthcare Corporation; and

12. Awarding Baxter Healthcare Corporation such other costs and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedures, Baxter Healthcare Corporation hereby demands a trial by jury on all issues triable of right by a jury.

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By: _____

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Dated: October 1, 2007

822364

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on October 1, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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I hereby certify that on October 1, 2007 I have sent by E-mail the foregoing document to the following non-registered participant:

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